DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2015

Synthes (USA) Products, LLC
Mr. Nicholas Fountoulakis
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K150099
Trade/Device Name: DePuy Synthes Variable Angle Locking Hand System (1.3mm and 2.0mm Plates and Screws)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 16, 2015
Received: January 20, 2015

Dear Mr. Fountoulakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150099

Device Name
DePuy Synthes Variable Angle Locking Hand System (1.3mm and 2.0mm Plates and Screws)

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle Locking Hand System is intended for fracture fixation of the hand and other small bones and small bone fragments, in adults and adolescents (12-21) particularly in osteopenic bone.

System indications include the following:
o Open reduction and internal fixation of fractures, mal-unions, and non-unions
o Following excision of benign bone tumors
o Replantations and reconstructions
o Arthrodeses of joints involving small bones
o Osteotomies, including deformity correction such as rotation, lengthening, shortening
o Pathological fractures, including impending pathologic fractures

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: March 13, 2015

Sponsor:	DePuy Synthes Nicholas S. Fountoulakis 1301 Goshen Parkway West Chester, PA 19380 Office: (610) 719-6553 Fax: (484) 356-9682
Proprietary Name:	DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws)
Classification:	Class II, HRS, §888.3030 – Plate, Fixation, Bone Class II, HWC, §888.3040 – Screw, Fixation, Bone
Primary Predicate Devices	K030310 – Synthes Stainless Steel Modular Hand System
Additional Predicate Devices	K063049 – Synthes (USA) Modular Mini Fragment LCP System K100776 – Synthes 2.4 mm/2.7 mm Variable Angle LCP Forefoot/Midfoot System K112583 - Synthes Cortical Screws
Device Description:	The DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws) consists of stainless steel and titanium plates and screws that offer screw-to-plate locking designed for various fracture modes of the hand. The plates and screws contained in the DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws) are offered in a range of configurations to accommodate patient anatomy and surgical need. The subject system contains two plate and screw sizes, 1.3 mm and 2.0 mm, general instruments, and device specific instruments. The 1.3 mm plates in this submission are designed to accept new 1.3 mm cortex and locking screws. The 2.0 mm plates are designed to accept existing 2.0 mm cortex screws, 2.0 mm locking screws, and new 2.0 mm Variable Angle (VA) locking screws. The new 2.0 mm VA locking plates and screws feature existing variable angle locking technology (K100776).
Indications for Use:	The DePuy Synthes Variable Angle Locking Hand System is intended for fracture fixation of the hand and other small bones and small bone fragments, in adults and adolescents (12-21) particularly in osteopenic bone. System indications include the following: • Open reduction and internal fixation of fractures, mal-unions, and non-unions • Following excision of benign bone tumors • Replantations and reconstructions • Arthrodeses of joints involving small bones • Osteotomies, including deformity correction such as rotation, lengthening, shortening • Pathological fractures, including impending pathologic fractures

Substantial Equivalence:	The proposed DePuy Synthes Variable Angle (VA) Locking Hand System (1.3 mm and 2.0 mm Plates and Screws) shares the same fundamental technological characteristics and intended use as the predicate Synthes systems (K030310, K112583, K063049, K100776). Fatigue strength testing was completed for the plates included in the subject system, demonstrating equal or greater strength in comparison to representative predicate plates. Plates were setup for fatigue strength testing in a plate-screw construct configuration that was intended to target the weakest portion of the plate by aligning the simulated fracture gap with the plate's smallest cross sectional area. New 1.3 mm Cortex and Locking Screws and 2.0 mm VA Locking Screws were tested using methods detailed in ASTM F543-13 in order to demonstrate performance in accordance with the specifications of the standard or in cases where a benchmark specification was not available, comparison was made to representative predicate devices. Literature has been provided to support the revision in indications, most notably the addition of the adolescent population Lastly, technological characteristics of the DePuy Synthes Variable Angle System such as locking holes, limited contact profiles, variable and standard locking technology, anatomic contours, and size ranges are prominent throughout the representative predicate systems. Based on the similarity of technical features across the predicate device, results of the performance data, and literature discussions, the subject DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws) is substantially equivalent to the predicate devices.